K010220

APR - 9 2001

510(k) Summary of Safety and Effectiveness

Statement	Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug, and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency. NEW DEVICE NAME: **Xtractor** PREDICATE DEVICE NAME: Endopouch pro specimen retrieval bag
Device Description	The **Xtractor** device is comprised of a flexible plastic bag with a large, easily accessible opening attached to a plastic rod. The handle and opening/closing mechanism allow single hand use.
Intended Use	The **Xtractor** is intended for use during general surgical procedures as well as the collection and extraction of tissue specimen such as appendix, gall bladder, biopsy specimen and other tissues and calculi.
Indications Statements	The **Xtractor** is a disposable device used as a receptacle for the collection and extraction of tissue specimens such as appendix, gall bladder, biopsy specimen and other tissues and calculi during laparascopic surgical procedures.
Technological characteristics	The new devices has different technological characteristics as the predicate device. The form and principle is different but the intended use is the same.
Performance Data	Animal and Human testing has been performed to verify that the **Xtractor** meets the performance required. It was determined that the device has a great bag strength and that the principle of operation is quicker than the predicate device.
Conclusion	Based upon the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the predicate device under the Federal Food, Drug, Cosmetic Act.
Contact	Martin Paquette Official Correspondant Groupe Horzone 411 Belvédère Sud Sherbrooke Québec Canada J1H 4B7
Date	January 22, 2001

Germain Béland
Président
Instruments Médicaux G.B. Inc.

Martin Paquette
Official Correspondant

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2001

Instruments Medicaux G. B., Inc.
c/o Mr. Martin Paquette
Groupe Horzone
411 Belvedere Sud
Sherbrooke, Quebec
Canada

Re: K010220
Trade/Device Name: Xtractor
Regulation Number: 876.1500
Regulatory Class: II
Product Code: GCJ
Dated: January 19, 2001
Received: January 24, 2001

Dear Mr. Paquette:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010220

Instruments Médicaux G.B. inc.
868 des Jardins Fleuris
Sherbrooke, Québec
Canada J1E 1J5
Téléphone : (819) 566-5689
Fax : (819) 820-9696

Indications for Use Statement

Ver 3 - 4/24/96

Applicant: Instruments Médicaux G.B. inc.

510(k) Number (if known): _____

Device Name: Xtractor

Indications For Use:

Xtractor is a disposable device used as a receptacle for the collection and extraction of tissue specimens such as appendix, gall bladder, biopsy specimen, other tissues and calculi during laparascopic surgical procedures.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010220